

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/010663

International filing date: 30 March 2005 (30.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/557,846  
Filing date: 31 March 2004 (31.03.2004)

Date of receipt at the International Bureau: 20 May 2005 (20.05.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland  
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**APPLICATION NUMBER: 60/557,846**

**FILING DATE: *March 31, 2004***

**RELATED PCT APPLICATION NUMBER: *PCT/US05/10663***



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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 380569352 US

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TITLE OF THE INVENTION (280 characters max)					
METHODS AND APPARATUS FOR MONITORING THE CARDIOVASCULAR CONDITION OF PATIENTS WITH SLEEP DISORDERED BREATHING					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	<input type="text" value="12"/>	<input type="checkbox"/> CD(s), Number	<input type="text"/>	
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	<input type="text" value="4"/>	<input checked="" type="checkbox"/> Other (specify)	<div>return itemized postcard</div>	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
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Respectfully submitted

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Date 3/31/04

REGISTRATION NO.  
(if appropriate)  
Docket Number:

44,617

3869/041

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16367 U.S. PTO

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Number 1 of 1

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PATENT  
Docket No. 3869-041

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Michael Farrell et al.

Serial No.: To Be Assigned

Filed: Herewith

For: METHODS AND APPARATUS FOR MONITORING THE CARDIOVASCULAR  
CONDITION OF PATIENTS WITH SLEEP DISORDER BREATHING

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Transmittal Letter for filing Provisional Application for Patent under 37 CFR 1.53(c); Twelve (12) pages of the Specification; Four (4) sheets of Drawings (Figs. 1-4); Check for \$160.00 (filing fee); and Return Receipt Postcard.

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## **METHODS AND APPARATUS FOR MONITORING THE CARDIOVASCULAR CONDITION OF PATIENTS WITH SLEEP DISORDERED BREATHING**

### **Field Of the Invention**

5           The invention relates to methods and apparatus for treating and monitoring sleep disordered breathing in patients with cardiovascular disease or otherwise monitoring the cardiovascular condition of SDB patients.

### **Background of the Invention**

10           "Sleep-disordered breathing" (SDB) generally refers to types of breathing disruption that occur during sleep. The most common form of sleep-disordered breathing (SDB) is obstructive sleep apnea (OSA). OSA affects approximately 20 million Americans—as many as asthma or diabetes. Less than 10% of people with OSA have been diagnosed and fewer treated. Loud, intermittent snoring, apneas, and hypopneas characterize OSA. Because the symptoms of sleep apnea present  
15 themselves as a result of a precursor, SDB has become the general term used to describe any disease state that manifests apneas and/or hypopneas during sleep. Apneas and hypopneas interfere with gas exchange, fragment sleep, and frequently cause oxygen desaturations. In severe cases, patients may experience these oxygen desaturations and arousals from sleep hundreds of times each night.

20           The most common treatment of SDB is to administer continuous positive airway pressure (CPAP). The use of nasal CPAP to treat OSA was invented by Sullivan and taught in U.S. Patent 4,944,310. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4-20 cm H<sub>2</sub>O. The air is supplied to the airway by a motor driven blower whose  
25 outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealed with the patient's face. More sophisticated forms of CPAP treatment may be provided by bi-level ventilators, proportional assist ventilators and servo-controlled ventilators. Such devices are typically used by the patient on a daily basis before and during sleep.

30           For example, nasal CPAP treatment of OSA may involve the use of an automated blower, such as the AUTOSET T™ device or AUTOSET SPIRIT™ available from ResMed Ltd. Examples of suitable nasal CPAP masks are the MIRAGE™ nasal mask and the MIRAGE™ full face mask also available from ResMed Ltd. The AUTOSET T™ device continuously monitors the state of the patient's airway  
35 and determines an appropriate pressure to treat the patient, increasing it or decreasing it as necessary. Alternatively, bilevel pressures are delivered to the patient as in the VPAP II™ devices also available from ResMed Ltd. Some of the principles behind the

operation of the AUTOSET T™ and VPAP II™ devices are described in U.S. Patent 5,704,345. The entire disclosure of U.S. Patent 5,704,345 is incorporated herein by reference. Other forms of pressure treatment are available such as that which is delivered in accordance with a smooth pressure waveform template and a continuous phase variable to provide comfortable pressure support substantially in phase with the patient's respiratory cycle. The device is the subject of U.S. Patent 6,532,957, the entire disclosure of which is hereby incorporated by reference.

In May 2000, a study in the New England Journal of Medicine indicated a profound link between SDB and hypertension, independent of other relevant risk factors. Hypertension as a disease has been estimated to afflict more than 25% of the population over 44 years of age. Left untreated, it leads to cardiovascular diseases such as heart attacks, stroke, coronary artery disease and heart failure. Collectively, cardiovascular disease (CVD) is now recognized as the major cause of death and disability in modern societies. With regard to the relationship between CVDs, studies have shown that over 60% of stroke, 50% of heart failure, 35% of hypertensive and 30% of coronary artery disease patients have SDB.

In general CVDs are diseases that have an impact on the correct functioning of the heart and blood vessels. In addition to cerebrovascular diseases (stroke), other significant CVDs include myocardial infarction (heart attack), congestive heart failure (CHF), transient ischaemic attacks (TIA) and peripheral vascular diseases, to name a few. As a whole it has been estimated that about 17 million people die of CVDs annually. Early diagnosis and treatment of CVD can be a major factor in reducing mortality associated with CVD's.

CPAP devices have in the past been used for the treatment of SDB in CVD patients. In one such device a form of pressure treatment has been directed at treatment of cardiac failure and Cheyne-Stokes breathing. In a device designated AUTOSET CS™, also provided by ResMed Ltd., pressure support is varied in phase with patient respiration in such a manner to oppose the waxing and waning changes in patient respiration that characterize Cheyne-Stokes breathing. The device is the subject of U.S. Patent 6,532,959, the entire disclosure of which is incorporated herein by reference.

As disclosed by Farrell et al. in the patent to U.S. Patent no. 6,336,454, CPAP treatment has also been recognized as a beneficial treatment of stroke. The use of CPAP treats stroke patients by improving arterial blood oxygen levels and reducing arterial carbon dioxide levels as well as improving auto-regulation of, for example, blood pressure, cardiac output and ventilation. Improvements in morbidity, such as

rate and degree of recovery of vital signs and patient stabilization in the acute phase, is an expected benefit.

Also, U.S. Patent 5,794,615 teaches a system including methods and apparatus for treatment of congestive heart failure (CHF). The system involves  
5 applying separate and independent gains to flow rates of pressurized gas delivered to a patient during inspiratory and expiratory phases of a respiratory cycle. The pressure support is disclosed as reducing cardiac pre-load and after load.

In short, there are many devices that can be used for treating SDB in patients that have cardiovascular disease. Nevertheless, despite a recognized need for early  
10 treatment or diagnosis of CVD patients and a lack of complete understanding of the mechanics of these diseases, little has been done to take advantage of the patient information monitoring potential of such CPAP devices that would exploit the substantial presence of these devices in the lives of SDB patients who may also be CVD patients or potential CVD patients. In short, there exists a need to track or  
15 monitor information related to such patients that would promote early treatment and diagnosis of CVD as well as further the understanding of SDB.

#### **Summary of the Invention**

It is an objective of the invention to provide methods and apparatus for treating respiratory disorders in cardiovascular disease patients or potential cardiovascular  
20 disease patients.

It is a further objective to provide methods and apparatus that assist in the management or monitoring of the cardiovascular condition of such patients to assist with diagnosis or treatment of related diseases.

Other objectives will be apparent to those skilled in the art from a review of the  
25 description of the invention as contained herein.

In accordance with one aspect of the invention there is provided apparatus comprising a sleep disordered breathing treatment unit and a unit for monitoring the patient for indications of cardiovascular disease.

The invention provides methods and apparatus useful for cardiovascular  
30 disease patients or potential cardiovascular disease patients with sleep disordered breathing. Preferably, the device is capable of delivering positive airway pressure at therapeutic levels for treatment of sleep disordered breathing. The device can be configured with one or more protocols that may be utilized in the provision of such pressure treatment. Over the course of one or more sessions of such treatment, the  
35 device may be configured to detect and record events associated with sleep

disordered breathing, such as, apnea, hypopneas, partial obstruction, snoring, pressure verse time, flow verses time, and leak for future analysis.

Additionally, the device is configured to detect or prompt and accept as input additional information concerning the cardiovascular condition of the patient including, for example, blood pressure, heart rate, oximetry data, electrocardiogram data, Holter Analysis results (including arrhythmia, heart-rate variability summaries), body mass index (including height and weight data), Left Ventricular Ejection Fraction (LVEF), six-minute walk data, B-type natriuretic peptide (BNP), cardiac output data, VO<sub>2</sub> max data, New York Heart Association Class (NYHA), ACC/AHA Heart Failure Stage, Quality of Life data (including, for example: Epworth Sleepiness Scale, Berlin Questionnaire, Minnesota Living with Heart Failure Questionnaire, Kansas City Cardiomyopathy Questionnaire), peripheral arterial tone (PAT), Key neuro-hormonal levels (e.g., catecholamine levels).

Such data may be continuously or periodically recorded or entered into the device relative to time. With such data in the device associations may be observed or made between the cardiovascular information and sleep disordered breathing related events on a common time scale so that changes that occur approximately or substantially in common may be observed or tracked. Such data may be retrieved from or viewed on the device or accessed remotely by a physician or clinician for purposes of monitoring or diagnosis of the patients SDB and/or a potential CVD.

Other aspects of the invention are described in the following detailed description.

#### **Brief Description of Drawings**

FIG. 1 shows an apparatus according to the invention;

FIG. 2 is a flow chart of an embodiment of a method for monitoring patient cardiovascular information;

FIG. 3 is a flow chart for an example of an SDB Screening & Unattended Sleep Diagnostic study that may be implemented with a method or apparatus of the invention;

FIG. 4 is a flow chart for an example of an SDB Screening & Attended Sleep Diagnostic study that may be implemented with a method or apparatus of the invention.

#### **Description of the Invention**

In reference to FIG. 1, the invention involves a pressure delivery device that may include a servo-controlled blower 2, a mask 6, and an air delivery conduit 8 for connection between the blower 2 and the mask 6. Exhaust gas is vented via exhaust

13. Optionally, a flow sensor 4f and/or pressure sensor 4p may also be utilized in which case mask flow may be measured using a pneumotachograph and differential pressure transducer or similar device to derive a flow signal  $F(t)$  and mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal  $P_{\text{mask}}(t)$ . The pressure sensor 4f and flow sensor 4p have only been shown symbolically in FIG. 1 since it is understood that those skilled in the art would understand how to measure flow and pressure. Flow  $F(t)$  and pressure  $P_{\text{mask}}(t)$  signals are sent to a controller or microprocessor 15 to derive a pressure request signal  $P_{\text{request}}(t)$ . Alternatively, a flow signal  $f(t)$  and pressure signal  $P_{\text{mask}}(t)$  may be estimated or calculated in relation to the blower motor by monitoring current supplied to the motor and/or the speed of the motor as disclosed in U.S. Patent nos. 5,740,795, 6,332,463 or 6,237,593 without the provision of flow and pressure sensors as described above. Optionally, the blower motor speed may be held generally constant and pressure changes in the mask may be implemented by controlling an opening of a servo-valve that may variably divert/vent or deliver airflow to the mask.

A controller 15 or processor is configured and adapted to implement the methodology described in more detail herein and may include integrated chips, a memory and/or other instruction or data storage medium. For example, programmed instructions with the control methodology may be coded on integrated chips in the memory of the device or such instructions may be loaded as software. With such a controller, the apparatus can be used for many different pressure treatment therapies simply by adjusting the pressure delivery equation that is used to set the speed of the blower or to manipulate the venting with the release valve.

The apparatus preferably also includes a communication port or module 10, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as hand-held display and control devices 12. The apparatus may further include additional interface 16 for connection to additional diagnosis or patient information gathering devices. For example, a diagnosis unit may optionally include a pulse oximeter 20, respiratory movement sensors 22 such as a chest band, EEG & ECG 24, EOG 25 and/or electrodes 28 for detecting cardiac rhythm. The oximeter may optionally be included in an oximeter in the main blower housing. There is a sense tube 14 connected to the main housing of the blower to the mask that allows the apparatus to sense oxygen concentration and pressure levels in the mask 6. Optionally, an automated  $\text{PCO}_2$  measurement device 21 or other non-invasive blood gas monitor/device for measuring  $\text{PCO}_2$  may be linked to provide an input data signal to the microprocessor 16, for example, a device as

taught in U.S. Patent Serial No. 5,630,413, the disclosure of which is incorporated by reference. Other automated measuring devices may also be included with the diagnosis unit as it relates to measuring other cardiovascular related information from the patient. In this regard, the device may, for example, be configured to  
5 communicate/receive such information from its own display (e.g. LCD screen) and input device (e.g., keypad or buttons) or via telemetry or other communication link from a blood pressure monitor, heart rate monitor, oximetry monitor, ECG device, ECG Event Monitor, Holtor monitor, automated tape measure, automated weight scale, treadmill device, blood analyzer device, cardiac output analyzer device, VO<sub>2</sub> max data  
10 device or Peripheral arterial tone assessment device. Those skilled in the art will recognize the types of information that may be generated by such devices.

Other optional input and/or output devices 22 may be included to display output signals and enter input signals for the microprocessor 16. Various appropriate input and output devices such as keypads and display screens and other alternatives are  
15 known in the art.

While this apparatus is generally described as a single unit, it is understood that a combination of devices and/or computers linked by any available communications method may be used to accomplish the goals of the invention. For example, the apparatus can interface with a variety of hand-held devices such as a  
20 Palm Pilot via wireless communication or it may interface with a network for transmission between the devices. With such a device or system, a physician may, for example, remotely monitor, analyze or record the status or data history of a patient. For example, remote devices may send to or retrieve from the apparatus any desired cardiovascular or other information. Such information may even be transmitted from  
25 the apparatus to a database of one or more patients. Furthermore, the treatment program that is being run on the patient can be monitored and changed remotely. In the event patient data is transmitted over open networks, the data may be encrypted for purposes of patient confidentiality.

#### Pressure Treatment Protocols

30 As illustrated by step 42 in the flow chart of FIG. 2, the apparatus incorporates various pressure treatment protocols that may be used to treat the condition of the patient. For example, in one mode, the device provides a generally constant pressure throughout a breathing cycle that may be therapeutic pressure or changes to such pressure set to treat SDB. In another mode, the apparatus provides a higher pressure  
35 to the mask during the inspiratory portion of the breathing cycle, a so-called IPAP (inspiratory positive airway pressure), and a lower pressure to the mask during the expiratory portion of the breathing cycle, a so-called EPAP (expiratory positive airway

pressure). Alternatively, the treatment delivered by the apparatus can smoothly vary in accordance with patient respiration to provide a smooth pressure waveform. For example, the device calculates a continuous phase variable to provide support in phase with the patient's breathing cycle and calculates the pressure to be delivered in accordance with a pressure waveform template. The delivery of such pressure is disclosed in U.S. Patent 6,532,957. Still alternatively, pressure may be supplied in proportion to patient respiratory airflow.

In yet another form, pressure support is varied in phase with patient respiration in such a manner to oppose the waxing and waning changes in patient respiration that characterize Cheyne-Stokes breathing. The methodology for such treatment is disclosed in U.S. Patent 6,532,959.

Optionally, the therapeutic pressure levels of the above protocols may be preset by a clinician or may be automatically adjusted or set by automatic detection of SDB related events, such as apneas (obstructive or central), hypopneas, partial obstruction, snoring, etc. as disclosed in US Patent 5,704,345 (Berthon-Jones). For example, the IPAP or EPAP levels may be adjusted by the automated determination to hunt for a minimal pressure that will be required to prevent or alleviate obstruction. Other alternative methods to vary the therapeutic level of the pressure for treatment to a patient and to detect SDB events may be utilized and are known in the art.

In providing these treatment methodologies, an accurate determination of respiratory airflow is important. Thus, the determined flow rate of air to the patient may be adjusted to account for the effect of leak. To this end, leak airflow may be determined by using a method such as taught in U.S. Patent 6,152,129 (Berthon-Jones), the entire disclosure of which is incorporated herein by reference. Leak data may also be recorded over time and stored in the device. Other known methods for determining leak may also be used by the device.

Other forms of pressure treatment will be known to those skilled in the art and may be implemented by the device.

#### Monitoring of Sleep Disordered Breathing Related Information

Preferably, the device provides efficacy tracking by detecting and recording or scoring SDB events or related information or indices over time, for example, by tracking or detecting central apneas, obstructive apneas, hypopnea, partial obstruction (e.g., flow flattening) or snoring. This is illustrated in step 44 of FIG. 2. Similarly, pressure and/or flow versus time data may also be recorded for analysis. In so doing, the device preferably performs compliance tracking in which the time on and time off of the mask are recorded with SDB related events for evaluation by statistical

summaries and charting. Methods for detecting and recording such information are known in the art, and may be implemented as described in U.S. Patent 5,704,345.

For example, the device may record AHI (apnea hypopnea index) over time or during particular time periods such as session-by-session, day-by-day, hour-by-hour, etc. In one embodiment of the invention an AHI scoring scheme may be implemented as follows:

- (i) An apnea is scored if a 2 second moving average ventilation drops below 25% of a recent average ventilation (time constant =100s) for at least 10 consecutive seconds,
- 10 (ii) An hypopnea is scored if the 8 second moving average drops below 50% but not more than 25% of the recent average ventilation for 10 consecutive seconds.

Similarly, the device may determine an index comparing central apneas verses obstructive apneas as disclosed in pending U.S. patent application no.10/014,684 (also in PCT/AU01/01595), the entire disclosure of which is incorporated by reference herein.

These events may be recorded with the time they occur or added to a total for a particular time period. Those skilled in the art will recognize other methods or modifications for detecting sleep disordered breathing information such as hypopneas or apneas and determining an AHI over time or within time periods.

#### Monitoring of Cardiovascular Condition

As previously noted and illustrated in step 40 of FIG. 2, the device is configured to receive information relating to cardiovascular information for the patient. Thus, a device of the invention preferably includes input devices for receiving or recording such based on the condition of the patient, continuously or periodically, so that preferably, as illustrated in step 46 of FIG. 2, such information may be associated with changes in the sleep disordered breathing related information over time.

Embodiments of the invention may include automated measuring apparatus that can generate signals associated with the automatically determined cardiovascular information for a processor of the device. Alternatively, the device may be pre-programmed to prompt or query for such information on a display or from another remote device, before use and/or periodically such as monthly, after three or six months, or some other timed period which may be based on use of the device (e.g. after 30 nights of use etc.), so that such information may be measured or determined separately and input by a user on a keypad or other data entry device. In relation to

cardiovascular related questionnaire, queries may be pre-programmed into the device and appropriate responses can be input by the patient in response to prompting by the device.

5 In one embodiment, an apparatus of the invention may include automated blood pressure monitoring apparatus that may continuously or periodically monitor or measure blood pressure and record such information such as in an overnight summary versus time. Alternatively, the device may prompt for input of such information on a display and keypad without the provision of such an automated device. Such information may then be charted alone or in association with sleep  
10 disordered breathing related information or events, such as an AHI, on a comparable or similar time scale so that related changes may be observed or noted.

In one embodiment, the device may monitor and record heart rate and/or detailed echocardiogram data continuously or periodically. Such information may be detected by filtering cardiogenic flow from a respiratory flow signal as disclosed in US  
15 Patent 5,704,345 or by other available heart rate detector. By recording such information over time, alone or on a similar time scale as sleep disordered breathing information, changes in heart rate may be observed or associated with changes in sleep disordered breathing to assist in tracking the condition of the patient.

Similarly, various embodiments of the device may optionally measure, prompt  
20 for and/or record/monitor additional cardiovascular information including oximetry data, blood sugar data, blood pressure data, electrocardiogram data, Holter Analysis results (including, e.g., arrhythmia, heart-rate and/or variability summaries), Body Mass Index, height and weight data, Left Ventricular Ejection Fraction (LVEF), Six-minute walk data, B-type natriuretic peptide (BNP), Cardiac Output data, VO<sub>2</sub> max data, New York  
25 Heart Association Class (NYHA), ACC/AHA Heart Failure Stage, Quality of Life data (including, e.g., Epworth Sleepiness Scale, Berlin Questionnaire, Minnesota Living with Heart Failure Questionnaire, and/or Kansas City Cardiomyopathy Questionnaire), Peripheral arterial tone (PAT) and Key neuro-hormonal levels (e.g., catecholamine levels).

30 Depending on the nature of the patient using the device, some or all of the above-listed cardiovascular information may be monitored by the device. In this regard, the device may be configured to monitor all of this information but the physician can preset the device to select one or more of the features for particular patients, which will then be monitored during their use. In one embodiment, the device  
35 is pre-programmed with associated sets or groups of data selected from the cardiovascular information that are pertinent for specific cardiovascular patients. By selecting a particular patient type, the device can automatically be configured to

monitor the pertinent cardiovascular information from the associated set or group of monitored data without monitoring unnecessary cardiovascular information for the particular patient. For example, a hypertension patient may be monitored for blood pressure, heart rate and Body Mass Index or a heart failure patient may be monitored  
5 for LVEF, heart rate and cardiac output data, a diabetic may be monitored for blood sugar etc. Those skilled in the art will understand which cardiovascular information is preferably associated with the different types of cardiovascular patients.

With the collection of such cardiovascular information being managed by the pressure treatment device, for example, on a night-by-night or week-by-week basis as  
10 it relates to the particular information being collected, a physician or clinician may periodically access a substantial source of information for study or analysis, as illustrated by step 48 of FIG. 2. Preferably, the cardiovascular and SDB information may be periodically remotely transferred to the physician or it may be accessed directly through displays on the device. In this way, a physician may keep up with and  
15 observe the changing cardiovascular condition of the patient with minimal direct oversight or intervention. Optionally, the device can be programmed with thresholds for comparison to the recorded cardiovascular information to trigger an alarm or send a message or generate a warning for the user, clinician or physician either directly on the device, or remotely, for example, over a secure electronic network to a database.  
20 For example, if the recorded or detected heart rate falls below an acceptable level, a warning or alarm may be generated. Similarly, if changes in weight, arrhythmia, blood pressure, blood sugar, heart variability, ECG data, etc. are recorded, automated warnings, alarms or messages may be generated by the device and manual or automated changes to the control of the device may be made such as a change in  
25 treatment protocol or a change to the set of monitored cardiovascular information such that additional cardiovascular information may be monitored. For example, the device may switch from monitoring hypertension associated cardiovascular information to monitoring congestive heart failure associated cardiovascular information if changes in the hypertension related monitoring data suggest that the patient's cardiovascular  
30 condition is deteriorating. Similarly, the device's treatment protocol may switch from a standard bi-level protocol to one that delivers servo-controlled pressure changes intended to reduce waxing and waning changes associated with Cheyne Stokes breathing.

Monitoring patients is an important aspect of management of cardiovascular  
35 disease. In accordance with an embodiment of the invention, one can take advantage of the long-term use of nasal CPAP devices (almost every night for the rest of the

patient's life) to monitor patients for many years. Thus it is hoped that early detection can lead to improved outcomes of a patient.

While the invention has been described with various alternative embodiments and features, it is to be understood that the embodiments and features are merely illustrative of the principles of the invention. Those skilled in the art would understand that other variations can be made without departing with the spirit and scope of the invention. For example, cardiovascular related treatment or diagnostic devices may be implemented to query for or measure SDB related information for the purpose of detecting SDB or otherwise determining a relationship between the cardiovascular condition of the patient and SDB. For example, a Holter Monitor or cardiac event monitor may be configured or programmed to prompt a patient with an SDB questionnaire. Thus, in one embodiment, the device may prompt a user with such questions as:

1. Do you snore ?
2. Are you excessively tired during the day?
3. Do you wake during the night feeling breathless?
4. Have you been told you stop breathing during sleep?
5. Do you have a history of hypertension?

In response to the answers from the use input into the device, for example if yes to two or more of these questions is received, the device may record, transmit or generate a warning to the user or physician to consider referral to a clinician or other physician for the purpose of undertaking a sleep diagnostic study to access the potential for SDB. In a more complex embodiment, a more detailed assessment of SDB related information may be implemented by the device. For example, it may prompt for the following:

Gender: (Male or Female)

Age Group: 18-39 40-59 60-79 80+

Height: (feet, inches)

Weight: (pounds)

1. Do you snore regularly?
2. Are you excessively sleepy during the day?
3. Do you wake during the night feeling breathless?
4. Have you been told you stop breathing during sleep?
5. Do wake up feeling un-refreshed after a night's sleep?
6. Do you have a history of hypertension?
7. Is the patients BMI > 30?

The number of positive responses may be tallied by the device to generate a SDB index which may be reported to a physician with a warning or other message. Alternatively, the SDB index may be compared to one or more thresholds and the degree of the need for a follow-up SDB study may be contained in a message or warning to the physician or user. For example, if the tally is 1 or 0, the message may identify that there is a low likelihood that the patient has an SDB condition or would need to follow-up with a sleep study. A higher tally, such as a 4 or higher may result in a more significant or urgent warning message suggesting that there is a high or higher likelihood of SDB or a need for a full SDB assessment. Such data may be combined with other sleep disordered breathing data recorded by the device, for example, an AHI, if the device is configured to record such data and may be included in the message or warning to the physician or user.

Similarly, other cardiovascular related treatment or diagnostic device may be configured or programmed to make an assessment for SDB related information of the patient. For example, a blood pressure monitor, heart rate monitor, oximetry monitor, Holter Monitor or other ECG device or cardiac event monitor, automated tape measure, automated scale device for weight, treadmill device, blood analyzer device, cardiac output analyzer device,  $VO_2$  max data device, peripheral arterial tone device etc.

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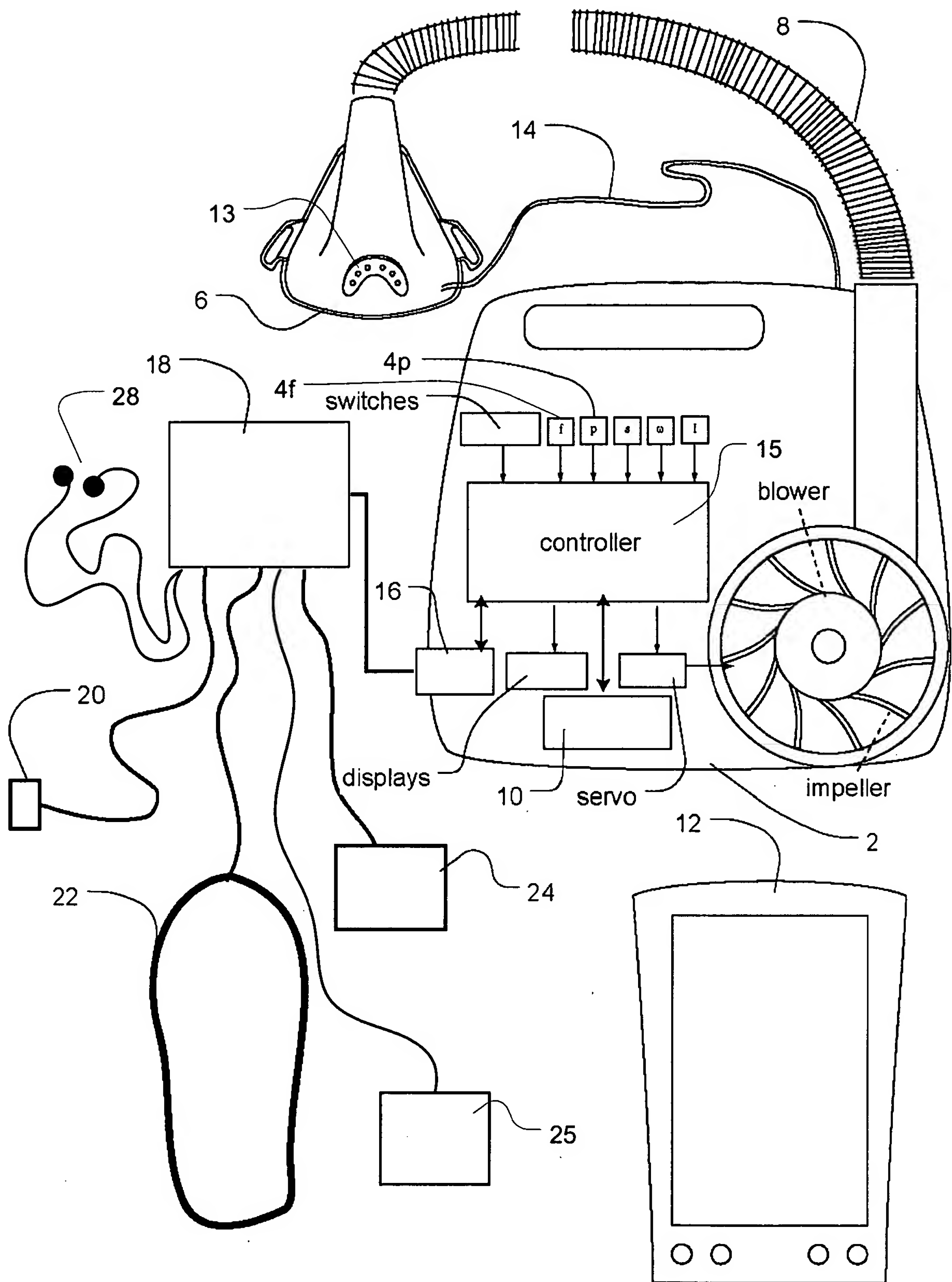


FIG. 1

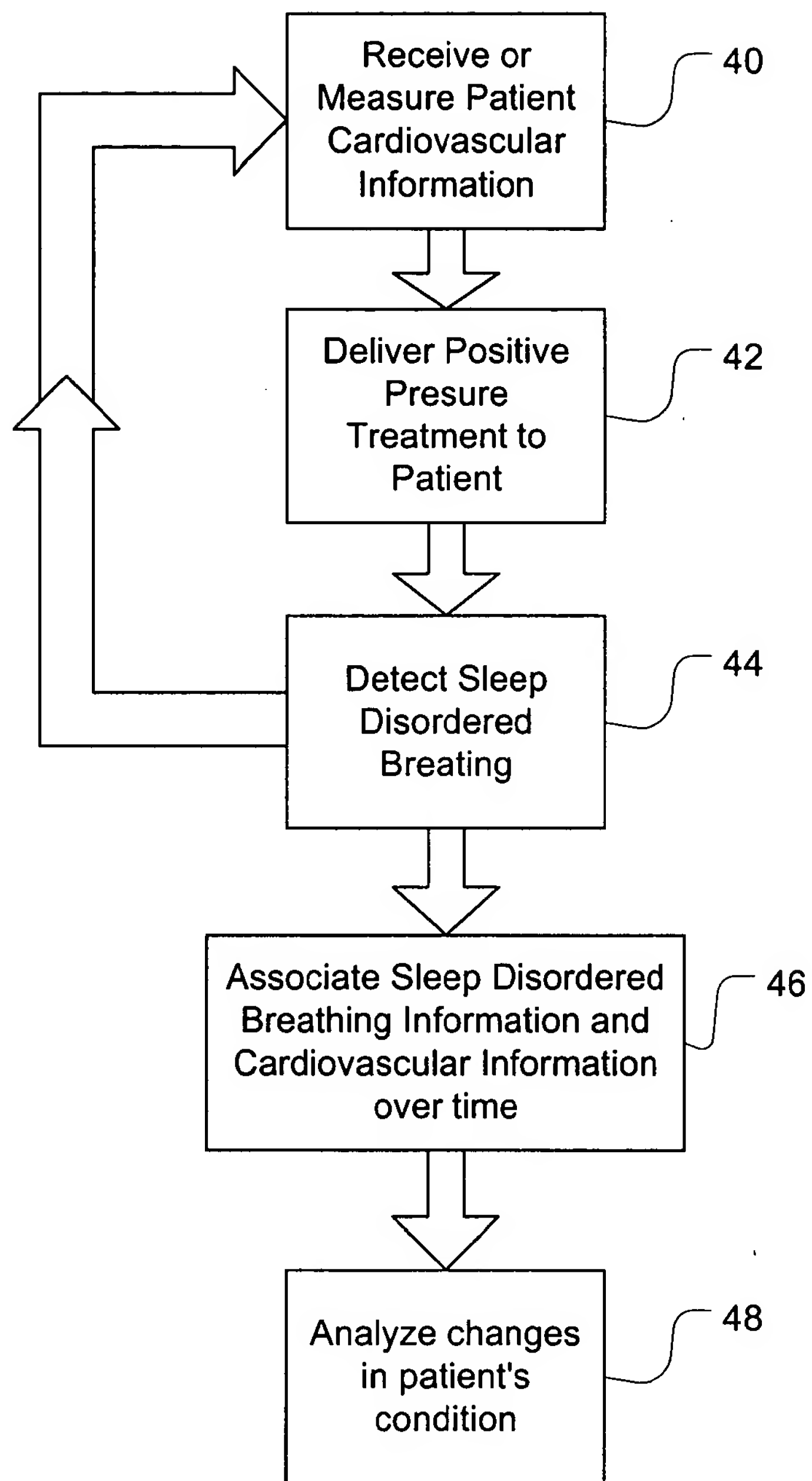


FIG. 2

Fig. 3

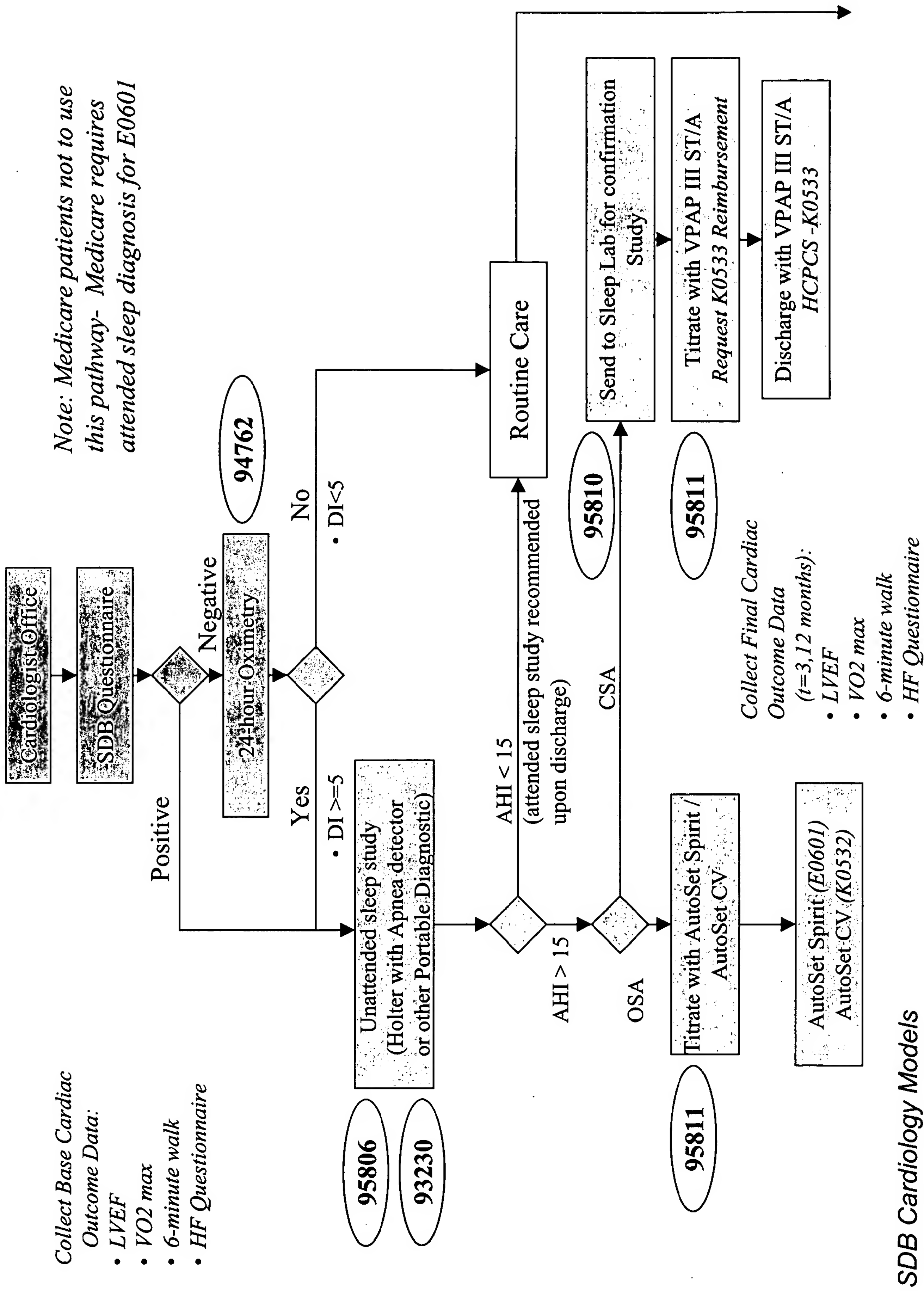


Fig. 4

